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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,600	10/03/2005	John Graeme Houston	9931-008US	7535
22897	7590	06/06/2007		
DEMONT & BREYER, LLC 100 COMMONS WAY HOLMDEL, NJ 07733			EXAMINER HOOK, JAMES F	
			ART UNIT 3754	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,600	Applicant(s) HOUSTON ET AL.	
	Examiner James F. Hook	Art Unit 3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, and 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Buscemi. The patent to Buscemi discloses the recited helical formation for a conduit comprising an elongate member (fig. 4) which is used with tubes such as vessels 10 comprising an inwardly extending portion 60 extending along the length of the elongate member from the internal side walls where the distance from the longitudinal axis of the tube is can include up to 50% depending upon the size of the vessel the member is provided in where such would be intended use, the conduit is seen to be circular in cross section, the extending portion extends inwardly a percentage of the radius, the helical formation is mounted to the wall and is a separate member inserted in the conduit, where such is used as a graft or stent in a blood vessel. Where such is made of a biocompatible material.

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer. The patent to Sawyer discloses the recited helical formation for a conduit comprising an elongate member which is used with tubes such as vessels 110 comprising an inwardly extending portion near 150 or 160 extending along the length of the elongate member from the internal side walls where the distance from the longitudinal axis of the tube is can include up to 50% depending upon the size of the vessel the member is provided in where such would be intended use, the conduit is seen to be circular in cross section, the extending portion extends inwardly a percentage of the radius, the helical formation is mounted to the wall and is a separate member inserted in the conduit, there are two or more extending formations provided side by side, where such is used as a graft or stent in a blood vessel.

Claims 1 and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kojima. The patent to Kojima discloses the recited helical formation for a conduit comprising an elongate member 19 which is used with tubes such as 16 comprising an inwardly extending portion 23,24 extending along the length of the elongate member from the internal side walls where the distance from the longitudinal axis of the tube is can be seen in figure 7 to extend toward the longitudinal axis between 10-80%, the conduit is seen to be circular in cross section, the extending portion extends inwardly a percentage of the radius, the helical formation is mounted to the wall and is a separate member inserted in the conduit, where such is provided with at least two side by side formations. The material used to form the article in Kojima is a stainless steel or

titanium material, and such are inherently biocompatible materials as such is a known property of the materials for use in forming articles used in the body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-8, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon. The patent to Simon discloses the recited helical formation for a conduit comprising an elongate member (fig. 6) which is used with tubes comprising an inwardly extending portion 12 extending along the length of the elongate member from the internal side walls where the distance from the longitudinal axis of the tube is seen to be about 50% of the distance, the conduit is seen to be circular in cross section, the extending portion extends inwardly a percentage of the radius, there are two or more inwardly extending formations arranged in side by side relation extending the length of the member, the helical formation is mounted to the wall and is in fact part of the wall, where such is used for flow where the use of such as a graft or stent are considered merely intended use where the structure is capable of use in a body. The patent to Simon discloses all of the recited structure with the exception of setting forth what type of plastic is used to form the article, however, it is considered merely a choice of mechanical expedients to choose any specific type of thermoplastic, including

polyurethane which is old and known in art to be a suitable thermoplastic material for making such articles, and such is inherently a biocompatible material, and it would have been obvious to one skilled in the art to use routine experimentation to arrive at an optimum type of thermoplastic to use for the article based upon the environment the article is to be used in as such would only require routine skill in the art.

Claims 1, 4-6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlmann (DE 597,472) in view of Kojima. The reference to Kuhlmann discloses the recited helical formation "a" defining a helix where such extends into the interior of the pipe "b" by at least 50%. The reference to Kuhlmann is for use in mixing materials but fails to disclose the recited use of a biocompatible material to form the article of. The patent to Kojima as set forth above recites forming a spiral mixing element of stainless steel or titanium as such is easy to manufacture with these materials. It would have been obvious to one skilled in the art to form the helical mixing article of Kuhlmann of any material including titanium or stainless steel as suggested by Kojima as such is a known material used to form helical mixing elements of that are used in high wear applications, and where such is easy to manufacture thereby saving manufacturing costs, where such is also inherently a biocompatible material.

Claims 7, 9, 10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlmann (DE 597,472) in view of Kojima as applied to claims 1, 4-6, 8, and 11 above, and further in view of Tayside (EP 1,254,645). The reference to Kuhlmann as modified discloses all of the recited structure with the exception of forming

the insert as a formation that is a removable insert with two or more extending formations that is used as a stent or graft. The reference to Tayside discloses the recited insert formed as an insert where at least two helical extending formations 12 extend in from an insert 11, and such is used as an insert into a blood vessel such as grafts and stents. It would have been obvious to one skilled in the art to modify the extending member in Kuhlmann as modified to be formed as an insert with at least two extending members formed therein and to use such as a graft or stent as suggested by Tayside as such are equivalent flow modifiers used in conduits and would provide a structure that would be less likely to deform thereby lessening its usefulness.

Response to Arguments

Applicant's arguments filed March 20, 2007 have been fully considered but they are not persuasive. With respect to the arguments directed at Kuhlmann such are moot based upon the new rejection above. With respect to the arguments directed at Schauburger, Jansen, and Ziegler, are moot based upon the rejections being dropped. With respect to arguments directed at Simon, such are moot based upon the new rejection above. With respect to the arguments directed at Buscemi and Sawyer, without an actual size limitation set forth in the claim, the percentage of the size of extent of the helical member in these references is relative to the size of the vessel in which the articles are disposed, and based upon the known sizes of the articles and vessels they are deployed in, smaller vessels would inherently lead to a 50% extent of the helical member from the conduit wall, therefore these arguments are not considered

persuasive. With respect to the arguments directed at Kojima, such is not persuasive when the claim language does not recite a medical context for the articles, and simply stating that the material used is biocompatible is merely an inherent property that any material would have that is also usable in a medical field and would not necessarily require the article be used in that field, merely that the material used is capable of use in that field. Therefore the recitation in Kojima that stainless steel or titanium can be used to form the article is disclosing a material that inherently is a biocompatible material as such is a property of the materials used to make the article in Kojima. With respect to the arguments directed at the 103 rejection, such is moot when the rejection under Kuhlmann has changed and does teach the required material which is the only argument directed at the 103 rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references to Klumb (122 and 237) disclosing state of the art stents which can act as flow modifiers.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3754

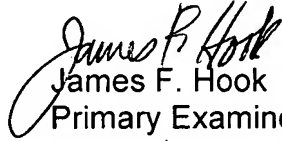
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James F. Hook whose telephone number is (571) 272-4903. The examiner can normally be reached on Monday to Wednesday, work at home Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


James F. Hook
Primary Examiner
Art Unit 3754

JFH